

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

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Consideration and examination of the above-identified application is respectfully requested.

Reconsideration of the restriction requirement is respectfully requested in view of the discussion below in this provisional election and preliminary amendment.

I. Provisional Election

The Restriction notes that generic claims exist among the pending claims 1-31, and that they will be examined for their full scope. However, a provisional election of a single nucleic acid is allegedly required under 35 U.S.C. § 121 and § 372 for those claims drawn to specific nucleic acid sequences.

The restriction of the examination of the claims of the subject patent application on the basis of the recitation of specific biological sequences is respectfully traversed on the grounds that claims at issue have the required unity of invention. It is respectfully submitted that there is a special technical feature linking the recited embodiments of the invention, contrary to the conclusion in the Restriction.

A shared special technical feature is not only that the recited nucleic acid molecule encodes all or part of an *E. coli* flagellin protein, but also that the molecule is capable of identifying the H serotype of an *E. coli* (other than *E. coli* H1, H7, H12 or H48 type strains) when hybridised to a gene of the *E. coli* which encodes a flagellin protein. This

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

is a contribution that the claimed invention makes over the prior art.

Because there are generic claims under consideration, no subject matter is cancelled or withdrawn from consideration at the present time. The generic claims encompass the full scope of the dependent claims reciting specific nucleic acid sequences.

The Restriction requires a selection of specific nucleic acid sequences for initial examination purposes of the claims reciting specific nucleic acid sequences. For dependent claims 3-6 and 30-31, SEQ ID NO:13 is provisionally elected. Claims 1-2, 7-19, 21-29. Note with respect to claims 12-13, 16-17, specific sequences of O antigens are recited, but the H antigens are still generic in scope as they are in Claim 11. If a specific sequence must be provisionally elected for claims 12-13 and 16-17, then it shall be SEQ ID NO:56. If a specific sequence must be provisionally elected for claim 20, then it shall be SEQ ID NO:57.

II. Recitation of Sequence Identifiers

The Restriction mailed October 8, 2002 also required amendment of the specification so as to identify each sequence recited using the assigned SEQ ID NOs, as required under 37 C.F.R. § 1.821(d), citing merely as examples of places where such references were lacking Tables 3A, 3B, 8, 8A, 9 and 9A, and claims 12, 16, and 24. The Examiner is thanked for bringing any deficiencies to our attention.

Claims 12, 16 and 24 referred to portions of the nucleic acid sequences as shown in Figures 5 and 6, which disclosed SEQ ID NOs 45 and 56, respectively. The reference

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

in the claims to the Figures were deleted, and in its place, the proper reference to the recited SEQ ID NO was incorporated. The support for the amendment is found in the Figures themselves as well as in the Brief Description of the Drawings discussing Figures 5 and 6.

Thus it is evident that no new matter is added by these amendments, and further, it is asserted that the subject matter in the amended claims does not go beyond the disclosures of the international application as filed, and thus, the full benefit of priority is unaffected.

With regards to Figures 5 and 6 themselves, the requirements of 37 C.F.R. § 1.821(b) as discussed in the Manual of Patent Examining Procedure (MPEP) Section 2422.02 notes that where sequences are disclosed in figures, "the sequence must still be included in the Sequence Listing and the sequence identifier ("SEQ ID NO:X") must be used, either in the drawing or in the Brief Description of the Drawings." Thus, the recitation of the SEQ ID NO in the Brief Description of the Drawings is sufficient to meet the Sequence Rules, so the Figures are not themselves amended at the present time.

With regard to the recitation of portions of the recited SEQ ID NO, the Examiner's attention is respectfully drawn to MPEP 2422.03 discussing sequences embedding the application text and variants of a presented sequence, where it is noted that "[s]equence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as 'residues 14 to 243 of SEQ ID NO:23' is permissible and the fragment need not be separately presented in the 'Sequence Listing.'" Thus, it is believed that the reference to the sequence

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

identifiers in claims 12, 16 and 24 meets the requirements of 37 C.F.R. § 1.821-1.825.

It is respectfully submitted that the requirements of 37 C.F.R. § 1.821(d) were met already with regard to Tables 8, 8A, 9 and 9A. The tables themselves already refer to SEQ ID NO:1 for Tables 8 and 8A, and SEQ ID NO:2 for Tables 9 and 9A. As to the various fragments thereof recited as primers, as discussed above, the reference to an included range of residues within a recited SEQ ID NO is permissible and the fragment need not be separately presented in the "Sequence Listing". Thus, no amendment of Tables 8, 8A, 9 and 9A were necessary to overcome the objection.

In view of the amendments and discussion above, it is respectfully requested objections to the application with regard to recitation of the assigned SEQ ID NOs be withdrawn.

III. Substitute Sequence Listing and Statement

In reviewing the application and biological Sequence Listing to address the objections noted in Section II above, it was noted that the primer sequences longer than 4 amino acids that are recited in Tables 3A and 3B were not included in the filed Sequence Listing as required by 37 C.F.R. § 1.821(d), and have not been previously assigned SEQ ID NOs.

As a result, a new substitute Biological Sequence Listing was created for the subject application. The diskette containing the Biological Sequence Listing computer-readable form (CRF) and a paper copy of the substitute Biological Sequence Listing accompanies this Provisional Election and Preliminary Amendment.

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

The present amendment incorporates the new SEQ ID NOs into the specification where needed. The amendments are shown in the copy of the substitute specification showing changes that is part of this Provisional Election and Preliminary Amendment. The addition of SEQ ID NOs and amendment of the sequence listing is fully supported by the disclosures in Tables 3A and 3B of the international application as filed, and thus no new matter has been added.

The paper copy of the substitute Sequence Listing required under 37 C.F.R. § 1.821(c) is enclosed, the sheets of which include no new matter, as required under 37 C.F.R. § 1.825(a). The present substitute Sequence Listing contains only subject matter included in the original national phase filing papers under 37 C.F.R. § 371 filed January 14, 2002. The Sequence Listing has the same disclosed subject matter as the above-referenced International Patent Application, and thus does not include matter which goes beyond the disclosed in the international application as filed.

Pursuant to 37 C.F.R. § 1.825(b), a substitute copy of the computer readable form (CRF), required by 37 C.F.R. § 1.821(e), is provided.

As required under 37 C.F.R. § 1.821(f), the sequence listing information recorded in the accompanying CRF is identical to the sequence listing information recorded in the accompanying written paper copy of the "Sequence Listing".

It is respectfully submitted that the present application is in complete compliance with the Biological Sequence Listing requirements of 37 C.F.R.

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

IV. Correction of Typographical Errors

Throughout the course of preparation of the present paper, several inadvertent obvious typographical errors were noted in the application. These errors have been corrected in the accompanying amendments, and are supported in the application as filed and in the parental international patent application. These amendments are shown in the accompanying copy of the substitute specification showing changes. These amendments do not substantively alter the scope of the disclosed subject matter, and it is evident that they add no new matter. One of these obvious, typographical errors that is corrected herein is the change from a to b the claims 24 and 25, which now parallel (and draw support from) claims 12-13 and 16-17, in that they recite the O antigens.

SUMMARY

Claims 1 through 31 are presently pending in the subject application.

It is believed that the application is in condition for allowance. An early allowance is earnestly solicited.

A fee for the Petition for an Extension of Time is enclosed. No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be a required petition.

U.S. Serial No. 09/701,132
PROVISIONAL ELECTION AND PRELIMINARY AMENDMENT
REMARKS

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By Shannon L. Nebolsky
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Attorney for Applicants

Enclosures:

Petition under 37 C.F.R. 1.136(a) and Fee
Substitute Specification
Substitute Biological Sequence Listing
Diskette
Postcard

US PTO Customer No. 24628

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CERTIFICATE OF EXPRESS MAILING

I hereby certify that this Provisional Election and Preliminary Amendment with Substitute Sequence Listing and Statement, together with a Petition under 37 C.F.R. 1.136(a) and its fee, and the stated enclosures, is being deposited with the United States Postal Service with United States Postal Service Express Mail Service with Express Mailing Label No. EL83355113US addressed to Commissioner for Patents, Washington, D.C. 20231, on April 8, 2003.

Shannon L. Nebolsky
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